MAR 3 1 2006

510(k) Summary

K 060255

E Surgical, LLC
1990 N. California Blvd., Suite 1040
Walnut Creek, CA 94596
925-280-8388 Phone
925-280-1788 Fax
Contact: Hans Richter, RA/QA Director

I. Trade Name: E Surgical
Electrosurgical Patient Return Electrode, Dual Plate with Cord
Electrosurgical Patient Return Electrode, Dual Plate Cordless

II. Common Name: Electrosurgical Patient Return Electrode

III. Classification: 21 CFR 878.4400, Electrosurgical Cutting and Coagulation Devices and Accessories

IV. Product Code: GEI

V. Indications for Use:
A single use, non-sterile dispersive electrode with or without a pre-attached cord to adhere to the patient over the entire pad surface to complete the electrosurgical circuit between the generator, the active electrode, and the patient.

VI. Predicate Device: Valleylab, Inc., VL 7600 REM Patient Return Electrode

VII. Device Description: The E Surgical Patient Return Electrode Dual Plate is a single use, non-sterile disposable electrode with and without a pre-attached cord. The use is to complete an electrical circuit during electrosurgery between the generator, the active electrode, and an adult patient.

VIII. Summary of Technological Characteristics: The E Surgical Patient Return Dual Electrode is comparable to the Valleylab, Inc.'s VL 7600 Dual Pad, REM compatible electrode, a legally marketed device. The E Surgical pad is furnished with a 9' cord or without a cord attached for use with a clamp accessory. The pad has a hydrogel adhesive for conductivity with an acrylic border to prevent invasion of fluids. Both pad designs are compatible with return electrode monitoring generator systems.

IX. Performance Data: The E Surgical Pad complies with the ANSI/AAMI HF-18 standard Electrosurgical Devices for Dispersive Electrode Thermal Safety and Contact Impedance. The pad design is proven safe by compliance to biocompatibility standard ISO 10993.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 1 2006

E Surgical, LLC.
c/o L.W. Ward and Associates, Inc.
Mr. Lewis Ward
4655 Kirkwood Court
Boulder, Colorado 80301

Re: K060255
Trade/Device Name: E Surgical Electrosurgical Patient Return Electrode, Dual Plate with Cord and Electrosurgical Patient Return Electrode, Dual Plate, Cordless
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI, JOS
Dated: January 25, 2006
Received: February 1, 2006

Dear Mr. Ward:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

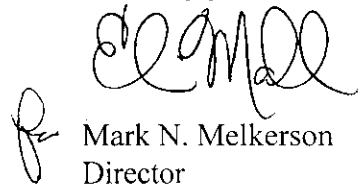
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K060255

Device Name: E Surgical Electrosurgical Patient Return Electrode, Dual Plate With Cord and Electrosurgical Patient Return Electrode, Dual Plate, Cordless

Indications for Use:

A single use, non-sterile dispersive electrode with or without a pre-attached cord used to adhere to the patient over the entire pad surface to complete the electrosurgical circuit between the generator, the active electrode, and the patient.

Prescription Use __X__ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K060255